山東新華製藥股份有限公司
Shandong Xinhua Pharmaceutical Company Limited

(a joint stock company established in the People's Republic of China with limited liability)

(Stock Code: 00719)

OVERSEAS REGULATORY ANNOUNCEMENT

This overseas regulatory announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Shandong Xinhua Pharmaceutical Co., Ltd. (the "**Company**") has published the "Announcement on Febuxostat Obtaining Notification of Approval of Marketing Application for Chemical Raw Material Drugs" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 10 October 2023, the English version of the relevant document is hereby included for reference. If there is any inconsistency between the English version and the Chinese version, the Chinese version shall prevail.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited
He Tongqing
Chairman

10 October 2023, Zibo, PRC

As at the date of this announcement, the Board comprises:

Executive Directors:
Mr. He Tongqing *(Chairman)*
Mr. Xu Wenhui
Mr. Hou Ning

Non-executive Directors:
Mr. Cong Kechun
Mr. Xu Lie

Independent Non-executive Directors:
Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Lo Wah Wai

Stock Code: 000756 Stock Short Name: Xinhua Phramaceutical Annoucement No.: 2023-40

Shandong Xinhua Pharmaceutical Company Limited

Announcement on Febuxostat Obtaining Notification of Approval of Marketing Application for Chemical Raw Material Drugs

The Company and the Board of Directors confirm that the contents of this announcement are true, accurate and complete without any false information, misleading statements or material omissions.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as "**Xinhua Pharmaceutical**" or the "**Company**") has recently received the Notification of Approval for Marketing Application for Chemical Raw Material Drugs（《化學原料藥上市申請批准通知書》）of Febuxostat (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

API Name: Febuxostat

Applicant: Shandong Xinhua Pharmaceutical Company Limited

Application Matter: Application for listing domestic production of chemical API

Reception Number: CYHS2160671

Registration Number: Y20210001232

Notification Number: 2023YS00658

Review Conclusion: According to the Drug Administration Law of the People's Republic of China, after examination, the Product meets the relevant provisions of generic drug approval, and the production of the Product is approved. Quality standards, packaging labels and production processes shall be carried out in accordance with the Notification of Approval for Marketing Application for Chemical Raw Material Drugs of febuxostat.

II. Other relevant information

In December 2021, Xinhua Pharmaceutical submitted the registration application materials for the domestic production of chemical raw materials by Febuxostat to the Center for Drug Evaluation of the State Drug Administration (藥品審評中心) and was accepted. In October 2023, Xinhua Pharmaceutical obtained Notification of Approval for Marketing Application for Chemical Raw Material Drugs《化學原料藥上市申請批准通知書》,and the review conclusion was approved for the production of the Product.

Febuxostat is a 2-arylthiazole derivative,a Xanthine oxidase inhibitor,which reduces the serum uric acid concentration by inhibiting the synthesis of uric acid. Febuxostat is taken orally and is suitable for long-term treatment of Hyperuricemia with gout symptoms. Febuxostat is highly selective and its effect is stronger than that of Allopurinol. It is mainly metabolized by the liver and does not rely on renal excretion and is safe and effective for patients with mild to moderate renal dysfunction, with minimal side effects and definite therapeutic effects.

Febuxostat belongs to the category B variety of the "National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog (2021)"(《國家基本醫療保險、工傷保險和生育保險藥

品目錄(2021年)》). According to relevant data, the global sales of Febuxostat related preparations in 2021 was USD787 million. In 2022, the total sales in Chinese public medical institutions and Chinese urban physical pharmacy terminals was approximately RMB 649 million.

III. Impact on the Company and risk warning

Febuxostat of Xinhua Pharmaceutical was approved for production in October 2023, which will help enrich the Company's API product categories and further enhance the Company's competitiveness in the API market.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest rationally and pay attention to investment risks.

By Order of the Board
Shandong Xinhua Pharmaceutical Company Limited

10 October 2023